

**DOLEX CHILDREN PAIN AND FEVER- acetaminophen suspension**  
**Pharmadel LLC**

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**Dolex Children Pain & Fever (APTA)**

***Drug Facts***

***Active ingredient & Purpose***

<b><i>Active ingredient (in each 5 mL)</i></b>	<b><i>Purpose</i></b>
<b>Acetaminophen 160 mg</b>	<b>Pain reliever/ fever reducer</b>

***Uses***

For the temporary relief of minor aches and pain due to:

- a cold
- headache
- sore throat
- toothache
- and to reduce fever

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- If your child is allergic to acetaminophen or any other of the inactive ingredients in this product

**Ask a doctor before use if your child has**

liver disease.

**Ask a doctor or pharmacist before use if your child is**

taking the blood thinning drug warfarin.

## When using this product

**do not exceed recommended dose (see overdose warning).**

### Stop use and ask a doctor if

- pain gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- redness or swelling is present

**Keep out of reach of children.**

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### Overdose warning:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

### Directions

- **this product does not contain directions or complete warnings for adult use**
- **shake well before using**
- **use only enclosed dosing cup. Do not use any other dosing device**
- mL = milliliter
- use the dose that corresponds to your child's age

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<b>Age (years)</b>	<b>Dose (mL)*</b>
under 2	consult a doctor
2 to under 4	5 mL
4 to under 5	7.5 mL
6 to under 8	10 mL
9 to under 10	12.5 mL
11 to under 12	15 mL

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\*Dose may be repeated every 4 hours while symptoms persist, up to five times a day or as directed by a doctor.

### Other information

- each 5 mL contains: **sodium 3 mg**
- store between 68-77° F (20-25° C)
- do not refrigerate

- **keep carton for full directions for use**

### ***Inactive ingredients***

anhydrous citric acid, butylparaben, FD&C red # 40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

### ***Questions?***

**+1-866-359-3478** (9 AM - 5 PM EST) or [pharmadel.com](http://pharmadel.com)

\*\* This product is not manufactured or distributed by Mcneil Consumer Healthcare, distributor of Children's Tylenol® Oral Suspension.

**Distributed by:**

**PHARMADEL LLC.**

New Castle, DE 19720

**Principal Display Panel**

NDC 55758-026-04

# DOLEX<sup>®</sup>

## Children's

# Dolor y Fiebre

### Pain & Fever

**Acetaminophen Oral Suspension**  
**Acetaminofén Suspensión Oral**  
—— 160 mg per/por 5 mL ——

**Pain Reliever,  
Fever Reducer**

**Alivia el dolor,  
Reduce la fiebre**



- ✓ Alcohol Free / Sin Alcohol
- ✓ Ibuprofen Free / Sin Ibuprofen
- ✓ Aspirin Free / Sin Aspirina
- ✓ For Ages 2 to under 12/ Para Edades 2 a menos de 12

COMPARE TO THE ACTIVE  
INGREDIENT IN CHILDREN'S  
TYLENOL<sup>®</sup> ORAL SUSPENSION\*\*

SE COMPARA CON EL INGREDIENTE  
ACTIVO EN SUSPENSIÓN ORAL  
TYLENOL<sup>®</sup> PARA NIÑOS\*\*



**Cherry Flavor**  
**Sabor a Cereza**

**4 fl oz (118 mL)**

## DOLEX CHILDREN PAIN AND FEVER

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55758-026
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-026-04	1 in 1 BOX	01/01/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/01/2023	

